Appendix A

Letter from Dr. Julie Louise Gerberding, Director
Centers for Disease Control and Prevention

and

Dr. Harold W. Jaffee, Director
National Center for HIV, STD, and TB Prevention

Centers for Disease Control
and Prevention (CDC)
Atlanta, Georgia 30333

April 22, 2003

Dear Colleague:

The prevention of perinatal HIV transmission requires routine HJV screening of all pregnant women and the use of appropriate antiretroviral and obstetrical interventions that begin during pregnancy. Together, these actions can reduce the rate of mother-to-child HIV transmission to 2 percent or lower. Recently, new data have emerged indicating that higher testing rates are associated with testing strategies that routinely incorporate HIV tests in the standard battery of tests for all pregnant women. In light of this information, the Centers for Disease Control and Prevention (CDC) recommends that HIV testing be a routine screening procedure. CDC also recommends implementing rapid HIV testing in postnatal settings for infants of women not tested prenatally. Considering the potential for preventing transmission, no child should be born in this country whose HIV status, or whose mother's status, is unknown.

CDC published data on recent prenatal HIV testing rates in the United States and Canada in the *Morbidity and Mortality Weekly Report (MMWR,.)* of November 15, 20022. This study examined HIV prenatal testing rates associated with three different prenatal testing approaches from data gathered from 16 states and 5 Canadian provinces. A brief description of the testing approaches and data findings follows:

1. *"Opt-in":* Pregnant women receive pre-HIV test counseling and must specifically consent to an HIV antibody test, usually in writing. This is the most common prenatal HIV testing approach in the United States Among eight states using the "opt-in" approach where data were collected from medical records for 1998—1999, testing rates ranged from 25 percent to 69 percent. Canadian testing rates in three "opt-in" provinces ranged from 54 percent to 83 percent.

2. *"Opt-out":* Pregnant women are notified that an HIV test will be routinely included in the standard battery of prenatal tests for all pregnant women, but they can decline HIV testing. Currently, Arkansas, Michigan, Tennessee, and Texas have adopted some version of this approach In Tennessee, where this approach was used, a testing rate of 85 percent was reported. Two Canadian provinces using this approach showed a testing rate of 98 percent and 94 percent.

3. *Mandatory newborn screening:* If the mother's HIV status is unknown at delivery, newborns are tested for maternal HIV-antibody, with or without the mother's consent. Results must be available within 48 hours of testing. Connecticut and New York have implemented these approaches (in combination with an opt-in approach for pregnant women). In these two states, data indicate that prenatal testing rates rose from 52 percent to 83 percent in a seven-county area of New York, and from 31 percent to 81 percent in Connecticut, during the periods just before and just after implementation of mandatory newborn testing. In 2001, New York reported a statewide prenatal HIV testing rate of 93 percent based on newborn metabolic screening of all live births.

Prenatal HIV Screening

Based on information presented in the MMWR, the available data indicate that both "opt-out" prenatal maternal screening and mandatory newborn screening achieve higher maternal screening rates than "opt-in" prenatal screening. Accordingly, CDC recommends that clinicians routinely screen all pregnant women for HIV infection, using an "opt-out" approach, and that jurisdictions with statutory barriers to such routine prenatal screening consider revising them.

Newborn HIV Screening

In addition, CDC encourages clinicians to test for HIV any newborn whose mother's HIV status is unknown. Jurisdictions should consider whether a mandatory screening policy for these infants is the best way to achieve such routine screening. Data demonstrate that detection of HIV infection during pregnancy through HIV testing of all pregnant women affords the best opportunity to deliver interventions when they are most efficacious. When intervention does not begin until the intrapartum or neonatal periods, 9 percent to 13 percent transmission rates are achievable based on clinical trial and observational data. Recent experience from the CDC funded Mother-Infant Rapid Intervention at Delivery (MIRIAD) study indicates that HIV rapid testing of women can be done during labor, and that antiretroviral interventions can be quickly delivered to HIV-infected mothers and their infants. Therefore, for those women whose HIV status is unknown at labor, CDC recommends routine, rapid testing. When the mother's HIV status is unknown prior to the onset of labor and rapid HIV testing is not done during labor, CDC recommends rapid testing of the infant immediately post-partum, so that antiretroviral prophylaxis can be offered to HI V-exposed infants.

The federal Food and Drug Administration has approved three rapid HIV test kits (SUDS Oraquick and Reveal which can be used at delivery When rapid test results are positive, antiretroviral interventions can be offered to the mother intrapartum and to her infant based on the preliminary results. Confirmatory testing should occur as soon as possible after delivery.

Sincerely,

Julie Louise Gerberding, M.D., M.P.H.
Director

Harold W. Jaffe, M.D.
Director
National Center for HIV, STD, and
TB Prevention

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Appendix B

Providing Information to Women in Labor with Unknown HIV Status Regarding Routine, Rapid HIV-1 Antibody Testing (Using an OPT-OUT Approach)

and

Sample Consent for Rapid HIV-1 Antibody Testing in Labor and Delivery Settings for Women with Unknown HIV Status (Using an OPT-IN Approach)

Providing Information to Women in Labor with Unknown HIV Status Regarding Routine, Rapid HIV-1 Antibody Testing (Using an OPT-OUT Approach)

Eligibility

Pregnant women in labor and delivery settings who have no documentation of HIV testing on prenatal record or no history of prenatal care.

How to Use This Script:

- The script is meant to be a guide to help you inform women in labor. Background information/instructions are in regular type, words you can use are in **italics –** *[italics are hard to read – suggest reworking – perhaps putting them in quotation marks.]*.
- It is important to show empathy while you are talking with the laboring woman – through your body language and/or through holding her hand /touch.
- Tell the woman she should signal you when a contraction is happening, so you can pause until it is over.
- Pause to verify understanding. Adjust your terminology as needed.
- Tell the woman that the discussion about HIV testing will be kept confidential.

Before discussing HIV testing, ensure that the woman is between contractions, that she is fairly comfortable, and that she is alone (no family member or significant other is present in the room, or within hearing). Tell her that you are going to talk to her about HIV testing, and ask if she wants her partner or family member to be present.

Introduction

You can begin the discussion in the following way:

We recommend HIV testing to all women in labor for whom we don't have records of an HIV test result during pregnancy. We do this because so much can be done to protect the babies of women living with HIV, and to help women live a healthier, longer life. We have no record that you had an HIV test during this pregnancy.

I have three things I am going to talk to you about:

- A special HIV/AIDS test
- Why this test is important for you and your baby, AND
- What happens when the test result comes back

A special HIV/AIDS test

- It is important for you and your baby that you have a "rapid" HIV test. HIV is the virus that causes AIDS
- This test can give us results **quickly**
- It is a blood test that we do for all women in labor without results from a prenatal HIV test unless they decline to have the test.

Why the test is important

- Human Immunodeficiency Virus (HIV) is the virus that causes AIDS
- HIV is a **serious** illness that can affect a woman's health and her baby's health.
- One of the ways HIV is spread is by unprotected sex. Therefore, **all** pregnant women may be at risk for HIV infection.
- HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
- If you **have** HIV infection, rapid testing will allow you to get medication during labor and delivery to reduce the risk of passing HIV to your baby.
- Your baby will receive the same medication after birth.
- **Without treatment**, the chance the baby will be infected is about 25%, or 1 in 4 babies.
- We **know** if women are given medication during labor and delivery and their babies get the medication right after birth, we can reduce the risk of HIV transmission to about 10%, or about 1 in 10 babies.

What happens when the rapid test result comes back?

- You will receive a **preliminary** result about an hour after your blood is drawn.
- If the rapid HIV test is **negative,** no further testing is needed at this time. It is **most likely** that you do **not** have HIV. However, the test may **not** show very recent infection.
- If the rapid test is negative it is OK to breast feed your baby.

If the rapid HIV test is positive

- You **likely** have HIV infection and your baby **may** have been exposed to HIV
- The test is a **screening** test that provides a preliminary result and a false-positive result can happen.
- We always do a second test to confirm rapid tests that are positive
- **To be safe, it is best** to start medicines to help prevent transmission of HIV to your baby, while we wait for the confirmatory test result
- Experts recommend several medicines to reduce chance your baby will get HIV. One is called AZT and it is given through your IV fluids into your vein. The other is a pill called nevirapine.
- Your doctor will decide which medicines will be best for you and your baby and will discuss them with you before starting them.
- After your baby is born, he/she will start taking AZT syrup.
- These medicines have been studied for in pregnant women and newborns and there have been no serious side effects.
- Side effects that may occur with AZT are: vomiting, headache, feeling tired, anemia (low red blood cell numbers), decreased number of white blood cells, that fight infection, loss of appetite, heartburn, trouble sleeping. Side effects of nevirapine can be skin reactions or problems with the liver.
- You should **wait** until we have the results of the confirmatory test before you start breastfeeding

If the confirmatory test is negative

- You and your baby will immediately be taken off any medication that was started

If the test is confirmed as positive

- All medication that was started to help prevent HIV transmission will continue.
- If treatment is started, a doctor or nurse will discuss again any consequences of taking the medication
- Your baby will need more testing for HIV infection
- You will be referred to a physician for your own medical care—there are also medications to help keep you healthy longer. You will also be referred to a health care provider who will take care of your baby's medical needs
- HIV test results are **confidential**. There are laws to protect people with HIV from discrimination.

Conduct rapid HIV testing and document the result clearly in the medical record.

If the woman declines HIV testing, probe for her reasons and help her address her concerns. If she still declines testing, document her refusal clearly in the medical record and communicate to her baby's pediatrician that her HIV status is unknown.

Sample Consent for Rapid HIV-1 Antibody Testing in Labor and Delivery Settings for Women with Unknown HIV Status (Using an OPT-IN Approach)

This is a sample consent form (OPT-IN) from the Francois Xavier Bagnoud Center for use in New Jersey. Recognizing that a number of jurisdictions may still require written, signed informed consent for HIV testing (an OPT-IN approach), this sample informed consent document may be useful during the transition to a more routine (OPT-OUT) approach to HIV testing in labor and delivery.

Introduction

New Jersey law mandates that all pregnant women be counseled about HIV infection and be offered the HIV/AIDS test. In our hospital, we follow this recommendation because so much can be done to protect the baby.

I have four things I am going to talk to you about

- A special HIV/AIDS test
- Why this test is important for you and your baby
- How HIV is transmitted
- What happens when the test result comes back

A special HIV/AIDS test

- It is important for you and your baby that we offer you what is called a "rapid" HIV test. Human Immunodeficiency Virus (HIV) is the virus that causes AIDS.
- This test can give us results **quickly.**
- It is a blood test. It is **voluntary,** and your consent is required before the test can be done.

Why the test is important

- HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
- If you **have** HIV infection, rapid testing will allow you to get medication during labor and delivery to reduce the risk of passing HIV to your baby.
- Your baby will receive the same medication after birth.
- **Without treatment**, the chance the baby will be infected is about 25%, or 1 in 4 babies.
- We **know** if women are given medication during labor and delivery and their babies get the medication right after birth, we can reduce the risk of HIV transmission to about 10%, or about 1 in 10 babies.

What is HIV and how is it transmitted?

- HIV is the virus that causes AIDS.

- HIV is a **serious** illness that can affect a woman's health and her baby's health.
- One of the ways HIV is spread is by unprotected sexual intercourse. Therefore, **all** pregnant women may be at risk for HIV infection.
- HIV can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.

What happens when the rapid test result comes back?

- You will receive a **preliminary** result about an hour after your blood is drawn.
- If the rapid HIV test is **negative,** no further testing is needed at this time. It **most likely means** that you do not have HIV. However, the test may **not** show recent infection.
- If the rapid test is negative it is OK to breast feed your baby.

If the rapid HIV test is positive

- You **likely** have HIV infection and your baby **may** have been exposed to HIV.
- The test is a **screening** test that provides a preliminary result. A false-positive result can happen.
- We always do a second test to confirm rapid tests that are positive.
- **But if your test result is positive, it is be best** to start treatment to help prevent transmission of HIV to your baby, while we wait for the confirmatory test result
- We will need your permission to start medications if the preliminary test is positive.
- Experts recommend several medicines to reduce the chance your baby will get HIV. One is called AZT. We give it to you in your IV fluids through your vein. The other is a pill called nevirapine.
- Your doctor will decide which medicines will be best for you and your baby.
- After your baby is born, he/she will start taking AZT syrup.
- These medicines have been studied in pregnant women and newborns and there have been no serious side effects.
- Side effects that may occur with AZT are vomiting, headache, feeling tired, anemia (low red blood cell numbers), decreased number of white blood cells that fight infection, loss of appetite, heartburn, trouble sleeping. Side effects of nevirapine can be skin reactions or problems with the liver.
- You should **wait** until we have the results of the confirmatory test before you start breastfeeding.

If the confirmatory test is negative

- *You and your baby will immediately be taken off any medication that was started.*

If the test is confirmed as positive

- All medication that was started to help prevent HIV transmission will continue.
- If treatment is started, a doctor or nurse will discuss with you again any consequences of taking the medication.
- Your baby will need more testing for HIV infection.
- You will be referred to a physician for your on-going medical care. You will also be referred to a health care provider who will take care of your baby's medical needs.
- HIV test results are **confidential**. There are laws to protect the rights of people with HIV and prevent discrimination.

Sample Informed Consent Form

Please sign your name below once you have read (or have had explained to you) and understand:

1. Antiretroviral medication may reduce the risk of HIV transmission to my baby and this medication will be started if my preliminary HIV test result is positive.
2. A positive preliminary test will be confirmed with additional testing.
3. Refusing to be tested will not jeopardize my ongoing care or services.
4. I have been given written information about everything told to me.

❑ I consent to be tested for HIV infection using a rapid test

❑ If my preliminary HIV test is positive, I consent to have antiretroviral medication started during labor and for my baby after birth

❑ I decline to have rapid HIV testing at this time.

Name_____ Signature_____
(PRINT)

Date_____ Witness_____

Appendix C

The François-Xavier Bagnoud Center's Formula for Offering Routine, Rapid HIV Testing to Women in Labor with Unknown HIV Status

The François-Xavier Bagnoud Center's Formula for Offering Routine, Rapid HIV Testing to Women in Labor with Unknown HIV Status

(Based on the mnemonic "C^3R^3")

The three Cs represent *confidentiality, comfort,* and *consent*. The three Rs are *reasons* for the rapid test*, results,* and *"Rx"* for treatment, or medications to reduce mother to child transmission.

C^3

- ***Confidentiality**:* It is important to reassure the woman that the discussion about HIV testing will be kept confidential and that the information will not be shared with her partner or family without her permission.
- ***Comfort**:* The clinician should assess the woman's stage of labor, comfort level, and need for analgesics. Providers need to show empathy while presenting information about rapid HIV testing. The content covered should be short and to the point and should be explained between contractions. The clinician should ask the woman to signal for a pause when a contraction is starting. The clinician should always consider the woman's language and culture and, as needed, must adjust the terminology used. The clinician should make sure that the woman being counseled understands the content being covered by checking after each point is made and before beginning the next point to be sure she understands.
- ***Consent*** for testing and for antiretroviral treatment, if needed, in labor: Regulations, laws, and policies about HIV testing of pregnant women vary from state to state. Providers need to know and need to follow the laws and policies of their state. The minimum content that should be included in educating a pregnant woman about HIV rapid testing during labor is detailed next under *Reasons to test.*

R^3

***Reasons to test**:* The woman should be informed of the important reasons to get an HIV test during labor, and the crucial opportunity to prevent possible transmission of the virus to her unborn baby should be emphasized:

- HIV is the virus that causes AIDS. One of the ways HIV is spread is by unprotected sexual intercourse. Therefore, all pregnant women **are** at risk for HIV infection.
- A woman could be at risk for HIV and not know that she is at risk.
- The HIV virus can be passed from a mother to her baby during pregnancy, at delivery, and through breastfeeding.
- Learning that a woman has an HIV infection while she is still in labor gives her a crucial opportunity to reduce the risk of transmitting HIV to her infant; and, just as importantly, having this knowledge also ensures that both she and her baby receive the care and the treatment they need.
- HIV testing is recommended for all pregnant women. Hospital/national policy (and/or state law) recommends HIV testing for all women in labor with unknown HIV status.
- Unless the woman refuses to be tested, our hospital routinely does rapid HIV testing for all women in labor who don't already have an HIV test result in their medical record.

Results

- If she is tested for HIV during labor, a woman should be told when she will receive her test results.

- A negative HIV test result means a woman almost certainly does not have HIV infection at this time. A positive HIV test result means a woman likely has HIV infection even if she is feeling well. Further testing will be done after she delivers to confirm if she has HIV infection.
- A woman should be asked who she wants to be present when she receives her rapid HIV test result.

Rx – Medications

- Medications can reduce the risk of transmission of HIV to the baby. Without medication, the chance the baby will be infected is about 25%—or about 1 baby in 4 births could be infected with HIV. With the medications given to the woman during labor and to the newborn, the risk of HIV transmission can be reduced to about 10— or to about 1 baby out of 10 births.
- If a woman is found to have HIV infection, treatment is available to help keep her well.
- Any medication will be stopped if the confirmatory HIV test result is negative.

Appendix D

Boxed Case Studies:

Development of a Statewide Standard of Care: The New Jersey Experience

and

A Review of the Implementation of Perinatal HIV Rapid Testing Medical Center Of Louisiana, New Orleans

Development of a Statewide Standard of Care: the New Jersey Experience

Sindy M. Paul, M.D., M.P.H.

New Jersey is a high prevalence state for HIV disease, ranked fifth in the country in cumulative reported AIDS cases, third in the country in cumulative reported pediatric AIDS cases, and first in the country in the proportion of women among reported cumulative AIDS cases. Ninety-four percent of the pediatric AIDS and HIV cases are attributed to perinatal transmission.

The approach taken by the New Jersey Department of Health and Senior Services (NJDHSS) was to conduct a needs assessment to determine the major missed opportunity to reduce vertical transmission, develop a the standard of care in collaboration with stakeholders with consensus facilitated by meeting with stakeholders individually (i.e. meetings with the obstetrical society), dissemination of information, and evaluation of implementation and effectiveness.

Needs Assessment

The need for a statewide standard of care for women who present in labor with the delivery team unaware of her HIV status was determined based on several factors. These include

1) A review of missed opportunities that indicated that currently the major gap **[barrier?]** to maximal reduction of vertical HIV transmission in New Jersey is women who present in labor with unknown HIV status;
2) Advances in HIV diagnostic testing technology and medical management that led to recent national recommendations that women who present in labor with unknown HIV status should receive counseling, be offered rapid HIV diagnostic testing, and, if HIV positive, be offered short course therapy;
3) Results of a study that was conducted in the highest risk areas in New Jersey that determined that none of the hospitals providing obstetrical care had policies, procedures, or laboratory capability to provide counseling and offer rapid testing and short course therapy; and
4) Meetings with two ad hoc advisory committees of stakeholders.

Working with Stakeholders

- Two ad hoc advisory committees were developed and met to 1) determine if a statewide approach was appropriate and 2) to develop the prototype policy and algorithm that facilities providing obstetrical care could implement for women who present in labor with unknown HIV serostatus.
- One ad hoc advisory committee consisted of stakeholders responsible for writing and implementing the Standard of Care. This ad hoc advisory committee included representatives from the New Jersey Department of Health and Senior Services (Division of AIDS Prevention and Control and the Division of Family Health Services), obstetricians, pediatricians, Title IV providers, the New Jersey Family-Centered HIV Care Network, case managers, social workers, consumers, maternal and child health consortia, infection control professionals, the Academy of Medicine of New Jersey, the AIDS Education and Training Center, and Medicaid. This committee met three times. The unanimous decision was that a statewide Standard of Care was the best approach to take in New Jersey. The committee felt that the NJDHSS should be the lead on developing, disseminating, and evaluating the Standard of Care. In the fall of 2001, the NJDHSS approved the draft of the Standard of Care for Women Who Present in Labor With Unknown HIV Status, which was written with the ad hoc advisory committee.

- The second ad hoc advisory committee consisted of stakeholders responsible for facilitating implementation of the Standard of Care. This ad hoc advisory committee included representatives from the New Jersey Department of Health and Senior Services (Division of AIDS Prevention and Control and the Division of Family Health Services), the Medical Society of New Jersey, all three hospital associations in New Jersey, the Infectious Diseases Society of New Jersey, the New Jersey Association of Osteopathic Physicians and Surgeons, New Jersey Section of the American College of Obstetrics and Gynecology, the New Jersey Obstetrical and Gynecology Society, the New Jersey Section of the American Academy of Pediatrics, the New Jersey Academy of Family Physicians, pediatric and obstetrical providers with a high-volume client load. This committee met once and provided written comments on the draft Standard of Care. They concurred with the other committee that NJDHSS should take the lead on developing, disseminating, and evaluating the Standard of Care. The unanimous decision was that a statewide Standard of Care was the best approach to take in New Jersey.
- Individual meetings were held with some key organizations such as the New Jersey Obstetrical and Gynecology Society, the Infectious Diseases Society of New Jersey, Medicaid, the NJDHSS Laboratory Task Force, and the Association for Professionals in Infection Control and Epidemiology.
- A one-on-one meeting was held with a high-volume facility in a high-prevalence area to help ascertain the potential barriers to implementing a statewide Standard of Care.
- Support for the statewide Standard of Care was obtained from the Governor's Advisory Council on AIDS.

Identification and Overcoming Barriers

Several barriers were encountered in implementation of the standard of care. The first barrier was that the advisory committee members did not have enough information on rapid testing. To overcome this obstacle, a half-day continuing medical education conference with a didactic lecture on rapid testing by Dr. Bernard Branson from CDC and case studies of women who presented in labor with unknown HIV status preceded the advisory committee meeting. The committee then felt that they had enough information on rapid testing to proceed with development of the standard of care.

The second barrier was that providers were uncertain about the content of counseling for women in labor. To overcome this, a template counseling session was developed with assistance from focus groups composed of postpartum women. The template counseling session was disseminated statewide through five train-the-train sessions conducted in collaboration with all the local maternal-child health consortia.

The third barrier identified was that hospital laboratory directors were under the misimpression that preliminary positive rapid or expedited test results could not be given to the providers and patients. To overcome this, a fact sheet on rapid testing was sent to each hospital with other information related to the standard of care, information was provided in a series of lectures given statewide, and an article was published in New Jersey Medicine.

The fourth barrier was that some hospitals requested a template policy to use. This was provided to them.

Dissemination of the Statewide Standard of Care

A multimedia comprehensive approach is underway to disseminate the Standard of Care. This consists of free Internet-based continuing medical education (available at www.acadmed.org), publication of articles in New Jersey Medicine, publication of articles in AIDSLine, a laminated pocket card for providers, poster presentations, train-the-trainer sessions, and continuing medical education lectures statewide. A mailing was sent to the chair of pediatrics, the chair of obstetrics, the laboratory director, the infection control professional, the chief executive officer, the medical director, the head nurse for labor and delivery, the executive committee, the vice-president of risk management, and the emergency room director of each hospital. The information packet included a cover letter from the Deputy Commissioner, the Standard of Care, the laboratory alert, the laboratory algorithm, and information on continuing medical education and train-the-trainer sessions.

Evaluation

Evaluation will be conducted to look at process measures and outcome measures.

- Repeat the hospital survey to determine if the Standard of Care has been incorporated into hospital policies and procedures and identify barriers to its implementation
- Retrospective medical record review to evaluate the implementation and effectiveness of the Standard of Care
- Continuous evaluation of efforts to reduce vertical transmission through surveillance, survey for childbearing women, and special studies.

Funding

Funding to develop, disseminate, and evaluate the Standard of Care came from state and federal funds. These funds allowed NJDHSS to contract with the National Pediatric and Family HIV Resource Center to help develop the counseling session, conduct the train-the-trainer sessions, provide three of the continuing medical education programs, and evaluate the implementation and effectiveness of the Standard of Care.

Review of the Implementation of Perinatal HIV Rapid Testing
Medical Center of Louisiana, New Orleans
Robert T. Maupin, M.D.

This is a summary of the initial clinical experience with the SUDS assay, for obstetric rapid testing, at the Medical Center of Louisiana.

In October of 1998, the Medical Center of Louisiana, New Orleans (formerly Charity Hospital), initiated rapid HIV-1 screening for obstetric patients admitted to the labor and delivery unit without prior documentation of HIV status. This program was approved by the Hospital Executive Committee and was established in conjunction with the use of rapid screening for employee occupational exposures. The program was developed by the hospital's Infection Control Division to address disease prevention and health care delivery needs of a subgroup of obstetric patients shown to have a two- to threefold greater HIV seroprevalence as compared with patients receiving obstetric prenatal care in the hospital's clinics. As a standard of care, all obstetric patients presenting to the labor and delivery unit with an undocumented HIV serostatus are offered voluntary HIV testing. Patients at risk for delivery prior to the completion of conventional HIV testing were offered initial screening with the FDA-licensed Single-Use Diagnostic System Test (SUDS), a rapid enzyme-linked immunosorbent assay (EIA). Patient acceptance of HIV testing was documented with written informed consent based on hospital policy and standards of care and in accordance with State guidelines for HIV testing at public facilities. Request for SUDS testing are submitted via the computer laboratory entry system. Patients consenting for screening were tested concurrently with a conventional HIV EIA and the SUDS HIV-1 rapid assay. SUDS assay determinations were conducted in the hospital blood bank laboratory service. This laboratory resource was selected based on the presence of adequate technical staff on a 24-hour basis. A confirmatory Western blot was used to document a true positive HIV result. The results of the SUDS test are reported electronically via the computerized laboratory inquiry system and are read out as SUDS reactive or non-reactive, and patients are informed of their SUDS test result by their treating physician.

Patients with a positive SUDS test result were counseled by their treating physician about the implications of the presumptive HIV positive status and were counseled about options for intervention to reduce vertical transmission of HIV. Laboring patients were administered peripartum antiretroviral prophylaxis consistent with the Public Health Service (PHS) guidelines. Infants delivered to mothers with positive SUDS tests were considered HIV exposed and initiated postpartum antiretroviral prophylaxis consistent with the PHS guidelines. When conventional HIV test results were discordant with the SUDS test and failed to confirm infection, the newborn prophylaxis was discontinued. All mothers with a confirmed HIV infection and their HIV-exposed infants were referred for HIV primary care follow-up at time of hospital discharge. The results of all obstetric patients who underwent both conventional and rapid HIV testing were recorded in the Office of Hospital of Infection Control's database.

Initial laboratory implementation and training was accomplished over several months. Blood bank technologists participated in a half-day "hands on" training session conducted by a SUDS vendor representative. Validation testing was conducted on site at the Medical Center of Louisiana, New Orleans Blood Bank Laboratory. The validation laboratory protocol required running 100

"unknown" serum samples with positive and negative controls. Compliance with accreditation guidelines required an evaluation of the new testing program with a proficiency testing survey. Subscription to the Wisconsin State Lab of Hygiene HIV Survey for HIV-1/2, formerly the Health Care Financing Administration (now called Centers for Medicare and Medicaid Services) approved and vendor recommended, was acquired to meet these requirements. The initial implementation cost of the hospital program for SUDS testing was approximately $2,000.

An examination of the Hospital's perinatal HIV rapid testing program through the first 12 months demonstrated a SUDS test performance with a sensitivity and specificity of 100% and 99.2%, and positive and negative predictive value of 79% and 100%, respectively. The overall seroprevalence in the tested population was 2.9%. The positive predictive value of the SUDS assay was highest among laboring women with inadequate prenatal care and an undocumented HIV status, which represented the highest seroprevalence group (>5%).

An evaluation of the initial clinical experience with perinatal HIV rapid testing demonstrated that nearly 20% of the HIV exposed births at the facility were identified through rapid testing. The majority of these mothers had inadequate or absent prenatal care. All SUDS positive laboring mothers with a subsequent confirmed positive HIV status had evidence of advance labor or rupture of membranes at admission. All of these mothers had inadequate prenatal care. Of note upon review of medical records, it was determined that as many as 50% these mothers had evidence of a positive HIV test prior to the current pregnancy, but did not disclose their HIV status to their treating physician at time of presentation. Intrapartum antiretroviral prophylaxis was successfully initiated in the majority of these mothers, and newborn prophylaxis was initiated for all infants prior to hospital discharge. All infants entered HIV primary care follow-up post hospital discharge. A preliminary assessment of a small number of HIV-exposed infants identified with HIV rapid testing demonstrated significantly reduced transmission rate in contrast to that expected among HIV-exposed infants without peripartum antiretroviral prophylaxis.

This medical center's experience highlights the capacity to effectively develop and implement targeted strategies for perinatal HIV rapid testing in a high-seroprevalence, obstetric population, and the potential impact of similar public health measures/interventions to reduce mother-to-child HIV transmission among childbearing women with an undocumented HIV status and poor prenatal care.